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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,836	04/25/2001	Bruce L. Roberts	GA0229	5822

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GENZYME CORPORATION
LEGAL DEPARTMENT
15 PLEASANT ST CONNECTOR
FRAMINGHAM, MA 01701-9322

EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,836

Applicant(s)

ROBERTS ET AL.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election of Group I, claims 1-6, with traverse, is acknowledged. Claims 1-20 are pending. Claims 7-20 are withdrawn from consideration, being drawn to non-elected inventions. Claims 1-6 are examined on the merits.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold *et al* (*J. Biol. Chem.* 274:19087-19094, 1999) in view of Scheicher *et al* (*Eur. J. Immunol.* 25:1566-1572, 1995). The claims are drawn to an adenovirus particulate comprising a plurality of adenovirus particles complexed to an insoluble micro-platform material, additionally comprising a cell binding ligand. The micro-platform material can be a polymeric fiber of microbead. The cell-binding ligand binds to a receptor on a dendritic cell and can be GM-CSF, mannose, or mannose-6-phosphate. The adenovirus particulate further comprises a gene encoding an antigenic polypeptide.

Diebold teaches mannose polyethylenimine conjugates for targeted DNA (ManPEI/DNA complexes) delivery into dendritic cells via the mannose receptor. Disclosed are dendritic cells transfected with ManPEI/DNA complexes that additionally contain adenovirus particles, Ad/ManPEI (abstract). Diebold teaches that adenovirus particles enhance the efficacy of

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ManPEI transfection and activate T cells of T cell receptor transgenic mice (figure 5, page 19092). Also disclosed is the use of Ad/ManPEI transfection for delivery of an OVA peptide (figure 7 and page 19091, second column). Diebold fails to teach an insoluble micro-platform material comprising a polymeric fiber or microbead.

Scheicher teaches the uptake of microparticle-adsorbed protein antigen by dendritic cells resulting in efficient antigen presentation (abstract). Conalbumin (CA) is adsorbed to polystyrene particles (insoluble micro-platform material) in the amount of 0.4 pg of CA per one FITC particle. Scheicher discusses the advantages of using an insoluble (bead-adsorbed) antigen presentation system for uptake and display in dendritic cells (page 1571, second paragraph). It would have been obvious to incorporate microbeads into Ad/ManPEI/DNA complexes. One would have been motivated by Scheicher's teaching that bead-adsorbed antigen carriers targeted to dendritic cells result in much more efficient antigen presentation than soluble antigen, as used by Diebold. One would have had a reasonable expectation of success that the bead-adsorbed system of Scheicher would work with Diebold's Ad/ManPEI/DNA complexes because mannose receptors are expressed in high levels on dendritic cells (Diebold, page 19087, second column, last paragraph) and Diebold's complex was able to target dendritic cells and display the antigenic polypeptide (OVA). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill at the time of the invention.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

3. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SBC

Stacy B. Chen
December 11, 2003

James C. Housel
JAMES HOUSEL 12/15/03
SUPERVISORY PATENT EXAMINER
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